K130453

510(k) SUMMARY

APR 0 2 2013

EyeKor EXCLESSIOR Software

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: February 19, 2013

Name of Device and Name/Address of Sponsor
EyeKor EXCELSIOR Software
EyeKor, LLC.
505 S. Rosa Rd.
Suite 10B
Madison, WI 53719

Common or Usual Name
System, Image Management, Ophthalmic

Classification Name
Camera, Ophthalmic, AC-Powered
21 C.F.R. 892.2050
Product Code: NFJ

Predicate Devices
Topcon Medical Systems Synergy (K093313)
Carl Zeiss Meditec Forum (K090439)

Intended Use
The EXCELSIOR Software is intended for use in importing, processing, measurement, analysis and storage of ophthalmic clinical images as well as in management of clinical data, through a computerized network for use in analysis of images and data obtained in clinical trials.

Device Description
The EXCELSIOR software is a cloud-based software that provides a grading platform integrating remote data collection, quantitative analysis and measurement, storage and management of ophthalmic data and images for clinical trials.

EXCELSIOR provides secure access through user authentication and role authorization, and is adherent to HIPAA and CFR 21 part 11 requirements for clinical investigations. EXCELSIOR user accounts can only be initiated by EXCELSIOR administrators or project managers: administrators or project managers enter in user information, and the user is prompted by email to setup his own user name and password. Once setup, the user access is defined by its role associated with a particular trial. EXCELSIOR provides 128-bit secure network encryption and audit trail logging to ensure that changes to the data are retraceable and re-constructible.

Performance Data
The EXCELSIOR Software has been tested and found in compliance with the following recognized consensus standard:

DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association. Specifies the format for the communication of digital images between individual devices and over networks.

Additionally, software validation and verification tests were performed which confirmed that the software performed as intended.

Technological Characteristics and Substantial Equivalence

The EXCELSIOR Software is intended for use in importing, processing, measurement, analysis and storage of ophthalmic clinical images as well as in management of clinical data, through a computerized network for use in analysis of images and data obtained in clinical trials. Both the identified predicate devices are ophthalmic image management systems intended for use in review and processing of ophthalmic images. Both EXCELSIOR and Synergy (K093313) are intended for use in importing, processing, measurement, analysis and storage of ophthalmic clinical images as well as management of data. Both systems receive the data through a computerized network. The differences between the intended uses primarily relate to the type of data being processed. In the case of EXCELSIOR, images and data related to subjects participating in a clinical trial is processed while Synergy processes data from patients in clinical practices. EyeKor believes that the similarity of the functions performed by the software products is sufficient to allow the intended uses to be determined to be similar.

The EXCELSIOR Software has very similar technological characteristics to the Forum and Synergy software programs. All of the software programs are client-server based applications with web-based viewing of ophthalmic images. All images are stored in a central database. All of the software programs are accessed from a PC using a Windows server operating system.

All of the software programs are built in a SQL database and support DICOM files for fundus photographs and OCT images. All of the systems support use of PDF files for reviewing ophthalmic reports. All of the systems allow the user to search for records related to a particular patient. One of the differences between the EXCELSIOR Software and the predicate devices is that images and reports accessed in the EXCELSIOR Software are accessed using subject identification numbers while Synergy and Forum access records based on the patient's name or other identifiable information. Since EXCELSIOR is used in a clinical trial environment this type of access is required.

In regards to measurements that may be made with the software programs, EXCELSIOR performs distance measurements, area measurements, ETDRS grid measurements, OCT layer thickness measurements, and macular grid summary. These are the same measurements performed by Synergy.

Therefore, the technological characteristics of the EXCELSIOR Software program are similar to the identified predicate devices.

In summary, the company's EXCELSIOR Software has a similar intended use as the previously cleared predicate devices. In addition, the EXCELSIOR Software has similar technological characteristics and principles of operation as its predicates. Although there are differences between EXCELSIOR and its predicate devices, those differences do not raise new questions of safety or effectiveness. Thus, the EXCELSIOR Software is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 2, 2013

EyeKor, LLC.
% Ms. Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K130453
Trade/Device Name: EXCELSIOR Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: February 20, 2013
Received: February 22, 2013

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130453

Device Name: EXCELSIOR Software

Indications for Use:

The EXCELSIOR Software is intended for use in importing, processing, measurement, analysis and storage of ophthalmic clinical images as well as in management of clinical data, through a computerized network for use in analysis of images and data obtained in clinical trials.

Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109 Subpart C) (Per 21 C.F.R. 807

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew Yang -S
2013.03.12 11:48:48 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K130453